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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/619,754 | 07/14/2003 | Birgit Bossenmaier | 39766-0114 A | 3323 |

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| EXAMINER | |
|---|---|
| HOLLERAN, ANNE L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1643 | |

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/619,754 | BOSSENMAIER ET AL. | |
| | Examiner | Art Unit | |
| | Anne L. Holleran | 1643 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, drawn to methods of identifying a tumor as responsive to an anti-Her-2 antibody, comprising detecting heterodimerization of Her-2, classified in class 435, subclass 7.1.

II. Claims 26-28, 50-52, and 71-73 drawn to methods of identifying a tumor as responsive to an anti-Her-2 antibody, comprising detecting ErbB phosphorylation, classified in class 435, subclass 7.1.

III. Claims 29 and 53, drawn to methods of identifying a tumor as responsive to an anti-Her-3 antibody, comprising detecting ErbB phosphorylation, classified in class 435, subclass 7.1.

IV. Claims 30 and 54, drawn to methods of identifying a tumor as responsive to an anti-Her-1 antibody, comprising detecting ErbB phosphorylation, classified in class 435, subclass 7.1.

V. Claims 31 and 55, drawn to methods of identifying a tumor as responsive to an anti-Her-4 antibody, comprising detecting ErbB phosphorylation, classified in class 435, subclass 7.1.

VI. Claims 32-39 and 56-63, drawn to methods of identifying a tumor as responsive to an antibody that inhibits the association of Her-2 with another ErbB receptor,

comprising detecting ErbB phosphorylation and Her-2 heterodimerization, classified in class 435, subclass 7.1

VII. Claims 74, 75 and 84-88, drawn to methods of treating a tumor, which has been determined to comprise a phosphorylated ErbB receptor, with an anti-Her-2 antibody, classified in class 424, subclass 130.1.

VIII. Claims 76-79, drawn to methods of treating a tumor, which has been determined to comprise Her-2 heterodimers, with an anti-Her-2 antibody, classified in class 424, subclass 130.1.

IX. Claims 80-83, drawn to articles of manufacture comprising an anti-Her-2 antibody, classified in class 530, subclass 387.1.

2. The inventions are distinct, each from the other, for the following reasons:

Claims 23-25, 40-49 and 64-70 link inventions II-V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 23-25, 40-49 and 64-70. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicant is advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims in the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination II has separate utility such as determining if a tumor would be responsive to an anti-Her-3, anti-Her-1 or anti-Her-4 antibody. See MPEP § 806.05(d).

Inventions II and III, IV or V are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, inventions II-V are distinct inventions because they are drawn to methods for determining the responsiveness of tumors to treatment with separate and distinct antibody species. For group II, the antibody is an anti-Her-2 antibody, which is an antibody that binds to a protein that is separate and distinct from any of Her-3, Her-1 or Her-4. Therefore, antibodies to Her-2 are separate and distinct from antibodies that bind any of Her-3, Her-1 or Her-4. Thus, each of the inventions, II, III, IV and V, have a materially different function and effect.

Inventions VII and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

case, the combination as claimed does not require the particulars of the subcombination as claimed because there are different methods for determining whether a tumor comprises a phosphorylated ErbB receptor. The subcombination has a separate utility such as determining whether a tumor will be susceptible to treatment with an anti-Her-3, anti-Her-1 or anti-Her-4 antibody.

Inventions VIII and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because there is a plurality of methods for determining whether a tumor comprises a Her-2 heterodimer. The subcombination has a separate utility such as determining whether a tumor will be susceptible to treatment with an anti-Her-3, anti-Her-1 or anti-Her-4 antibody.

Inventions VI and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because there is a plurality of methods for determining whether a tumor comprises Her-2 heterodimers. The subcombination has separate utility such as being used by itself for the purpose of determining whether a tumor is susceptible to treatment with an anti-Her-3, anti-Her-1 or anti-Her-4 antibody.

Inventions VI and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because there is a plurality of methods for determining whether a tumor comprises phosphorylated ErbB receptors. The subcombination has separate utility such as being used by itself for the purpose of determining whether a tumor is susceptible to treatment with an anti-Her-3, anti-Her-1 or anti-Her-4 antibody.

Inventions IX and VII or VIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the article of manufacture comprises an anti-Her-2 antibody that may be used in a method of detection of the Her-2 antigen or in a method of purifying the Her-2 antigen, both methods are materially different processes of using the product than the process of administering an anti-Her-2 antibody for the purpose of treating a tumor.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, it would be an undue burden on the examiner to search and examine the inventions together because each of the

methods has a different function and effect, requiring different searches of the non-patent and patent literature.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***In re Ochiai:***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn

process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
May 25, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER